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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,778	06/10/2005	Paula Belinky	29585	6857
7590	09/13/2007		EXAMINER SRIVASTAVA, KAILASH C	
Martin Moynihan Anthony Castorina 2001 Jefferson Davis Highway Sutie 207 Arlington, VA 22202			ART UNIT 1657	PAPER NUMBER
			MAIL DATE 09/13/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,778	BELINKY ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 June 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-68 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Preliminary amendment filed 10 June 2005 is acknowledged and entered.

Informal Matters

2. Please note that the correct Serial Number of your Application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) is 10/538,778, not "not Yet Known" as recited in Preliminary Amendment filed 10 June 2005. Please ensure that the correct U.S. Serial Number (i.e., 10/538,778) for this application is cited in all future correspondence with this Office.

3. Your application under prosecution at USPTO has been assigned in the Art Unit 1657. To aid in correlating any papers for this application (i.e., 10/538,778), all further correspondence regarding this application should be directed to Art Unit 1657.

4. The assigned Examiner to your application at the USPTO is Dr. Kailash. C. Srivastava. To aid in correlating any papers for this application (i.e., 10/538,778), all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

5. Please note, upon arrival at the United States Patent and Trademark Office (i.e., USPTO), each response/filing is sorted according to claims, remarks, amendment, transmittal etc. for scanning coding and incorporation in to the Electronic File Wrapper (i.e., IFW). In order to ensure that all the papers pertaining to a particular application are properly coded in the same application electronic file wrapper; and to further facilitate the prosecution; especially during a telephonic conversation/interview with applicant/applicants' representative, it is suggested that the following information be recited in the header of each page for any filing/response/amendment:

- a. Attorney Docket Number;
- b. First Applicant's name (e.g., Smith Jones et al.);
- c. Filing date for said application (e.g., 17 November 2002);
- d. U.S. Non-Provisional Application Serial Number (e.g. 00/000,000);
- e. Group Art Unit Number (e.g., 1657);
- f. Date of Office Action being responded to (e.g., 27 August 2006);
- g. Date of amendment/response (e.g., 27 April 2007); and
- h. Examiner's name (e.g., Dr. Kailash C. Srivastava).

Papers/responses filed according to above-stated guidelines immensely ameliorate the chances of papers lost during transaction/transmission, coding, indexing and placing the papers in IFW.

Claims Status

6. Claims 1-68 are pending.

Election /Restriction

7. This application contains the following groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372.

- Group I, consisting of claims 1-11, drawn to a Method and a composition (Claims 12-22) to apply “at least one type of a lignin modifying enzyme” to the “skin region or hair of a subject” to lighten skin region or hair of said subject comprising topically applying a cosmetic composition to the skin region or hair of said subject. Furthermore said composition comprises:
 - Isozyme H1, or a “modified form” of isozyme H2 of Lignin peroxidase at a concentration of at least “1U/gr.”;
 - An electron acceptor (e.g., hydrogen peroxide) at a concentration of at least 0.005%;
 - A *Cosmetically* acceptable carrier among: transcutol and/or butylenes glycol, or alkanol amines;
 - Veratryl alcohol at a concentration of at least 0.05%;
 - An epidermal penetrant, and
 - A type of hair penetrant.
- Group II, consisting of claims 23-34 drawn to a kit comprising a cosmetic composition and claims 35-41 drawn to “an article of manufacturing comprising a packaging material and a cosmetic composition”, said cosmetic composition having as active agent a Isozyme H1, or a “modified form” of isozyme H2 of Lignin peroxidase, wherein said composition is contained within said packaging material.
- Group III, consisting of claims 42-50 drawn to a method to lighten the “skin region of a subject via expressing a “lignin modifying enzyme” “within the cells of the skin region”.

- Group IV, consisting of claims 51-65 drawn to another method, said method comprising producing a lignin peroxidase via culturing *Phaenerochaete chrysosporium* on a porous matrix in a stirred and aerated culture medium.
- Group V, consisting of claims 66-68 drawn to another composition, viz. "an aqueous extract of *Phaenerochaete chrysosporium* fungus exhibiting lignin peroxidase enzymatic activity".

Inventions are Independent or Distinct

8. The inventions listed as Groups I-V, even though comprising common components, namely: a lignin peroxidase enzyme, do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of the inventive Group I invention is to lighten the skin region or hair of a subject (Claims 1-11) via applying a composition comprising a lignin peroxidase enzyme with the substrates for said enzyme (Claims 12-34). The inventive Group II despite having a common component, i.e., lignin peroxidase enzyme, is a kit that is distinguished from the compositions of inventive Groups I and V, because the special technical feature of the inventive Group II is the package in which the composition is contained and said composition may just be applicable for a diagnostic purpose. The distinguishing special technical feature of the invention in Group III invention is the method to express lignin peroxidase enzyme having via an expression vector, wherein said lignin peroxidase is "encoded by the polynucleotide sequence set forth in SEQ IDNO.1" in the skin cells of a subject, rather than the application of a composition comprising lignin peroxidase enzyme. The special technical feature of Group IV enzyme is a method to produce lignin peroxidase, whereas special technical feature of composition invention in Group V is the "aqueous extract" of *Phaenerochaete chrysosporium* having the lignin peroxidase activity. Thus, the special technical features of each of the inventions in each of Groups I-V is not the common component, i.e., lignin peroxidase, but the methods to apply said enzyme and produce it as well as the compositions comprising lignin peroxidase. Thus, inventions in each of Groups I-V do not share the same or similar technical feature. Since no special technical feature exists among the inventions in groups I-V, there is no unity of invention.

Species Election

9. This application contains claims directed to a variety of components. The search for each of the above inventions is not co-extensive, particularly with regard to the literature search. This is because the

inventive groups discussed above incorporate numerous components and numerous ingredients within each of the same, single invention. For example, to conduct a literature search for invention in Group I, one would be searching for a total number of combinations that will be a factorial of at least 5 components (i.e., counting all the different isozymes and cosmetically acceptable carriers) encompassing all the steps and the components with each one of the components/ingredients up to ingredient number 1 (i.e. 5*4, 5*3, 5*2, and 5*1). Thus, this group alone will exert an enormous search burden on the Examiner. Therefore, if the applicants elect invention of Groups I or II or IV or V above, applicants must also make election of species by electing one single species from each of the following categories (i.e., only one species from each category as applicable to elected group):

If applicants elect inventions in Groups I and II applicants must make an election of species as follows:

- a. only one isozyme among those listed in Claims 14, or 26 or 37; and
- b. only one cosmetically acceptable carrier among those listed in Claims 17 or 18 or 33 or 34.

If applicants elect inventions in Groups IV and V applicants must make an election of species as follows:

- c. only one isozyme among those listed in Claims 64, or 68.

The non-taxonomic species listed *supra* are independent or distinct because claims to the different non-taxonomic species recite the mutually exclusive characteristics of such non-taxonomic species. In addition, these non-taxonomic species are not obvious variants of each other based on the current record.

10. Applicants are required under 35 U.S.C. §121 to elect a single disclosed species for prosecution on the merit to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently Claims 1, 12, 22, 35, 42 and 51 are generic claims.

11. There is an examination and search burden for the above-mentioned patentably distinct species due to their mutually exclusive characteristics. The species require a special field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely raise different non-prior art issues under 35 O.K. §101 and or 35 O.K. §112, first paragraph.

12. **Applicants are advised that the reply to this requirement to be complete must include (I) an election of a species to be examined among the species listed in categories i-iv even though the**

requirement may be traversed (37 CFR §1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable, or that all claims are generic is considered non-responsive unless accompanied by an election.

13. The election of species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR §1.144. If claims are added after the election, applicant(s) must indicate which of these claims are readable on the elected species.

14. Should applicant(s) traverse on the ground that the species are not patentably distinct, applicant(s) should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other species. Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR §1.141.

15. In accordance with 37 CFR §1.499, applicants are required that a reply to this requirement must include an identification of the species that are listed in categories a-c *supra* and is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election of a Group and a corresponding species. If claims are added after the election, applicant must indicate which Claims are readable upon the elected species [MPEP §809.02(a)].

16. Applicants are reminded that upon the cancellation of claims to a non-elected invention and species, the inventorship must be amended in compliance with 37 CFR §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(I).

17. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in

accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR §1.116; amendments submitted after allowance are governed by 37 CFR §1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR §1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §101, §102, §103, and §112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. §121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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08 September 2007


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 128/P57